September 18, 2020

James E. Mathews, Ph.D.
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Dear Dr. Matthews:

On behalf of the National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB), we write in response to the Medicare Payment Advisory Commission's (MedPAC) public meeting held virtually on September 3, 2020. NILA and AAB's comments relate to the discussion entitled *Mandated Report: The Protecting Access to Medicare Act of 2014's changes to the Medicare clinical laboratory fee schedule.* As conveyed during our meeting with MedPAC on May 20, 2020, NILA and AAB member laboratories have experienced significant cuts in CLFS payment rates beyond what was anticipated due to the Centers for Medicare & Medicaid Services' (CMS's) flawed implementation of the Protecting Access to Medicare Act (PAMA). NILA is concerned that MedPAC's recent discussion explored ideas and concepts that would be detrimental to the laboratory industry and the patients we serve. NILA submits the following comments to MedPAC to help inform your work moving forward.

NILA and AAB members work in regional and community clinical laboratories across the United States and perform laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care professionals. NILA and AAB members serve a wide variety of communities and patient populations, many of whom are not adequately served by the largest independent laboratories—including rural areas, underserved inner city neighborhoods, mid- and small-sized cities and municipalities, congregate facilities, and critical access hospitals.

Increased Spending on Genetic Tests

Discussion at the September 3rd meeting included acknowledgment that new, high cost lab tests make up a significant portion of increased laboratory spending by the Medicare program. In fact, the increase in laboratory spending between 2017-2018 is entirely attributable to high-cost, genetic tests. According to the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG), overall Medicare spending on laboratory services rose by 6 percent, or $459 million.[1] During the same period, spending on genetic tests increased by $496 million—more than double the amount spent in 2017 and $37 million more than the *total* increase in Medicare spending on laboratory services. Setting aside genetic testing, Medicare spending on laboratory services actually fell between 2017 and 2018.

[1] Murrin, Suzanne, Deputy Inspector General for Evaluation and Inspections, U.S. Department of Health and Human Services Office of Inspector General, Medicare Laboratory Test Expenditures Increased in 2018 Despite New Rate Reductions, https://oig.hhs.gov/oei/reports/OEI-09-19-00100.pdf.

The increase in spending on genetic tests results from a choice by Congress to not inhibit the growth rate for these tests while slashing the rates for more common, lower cost tests.

While genetic tests are valuable health indicators for Medicare beneficiaries and their health care teams and play an important role in the future of diagnostics, reimbursement for these tests should not come at the expense of routine tests that serve an essential and cost-effective role in medical decision-making. The OIG acknowledges, "even a small number of inappropriate tests could expose Medicare to extremely high spending" and suggests that as the volume of these tests grows, oversight will become more important. The structure of PAMA essentially guarantees large increases in reimbursement for genetic tests at the expense of lower cost tests. Policy solutions to address Medicare spending should, therefore, address the source of the spending growth rather than other lower-cost tests that are not driving increases in spending. MedPAC must ensure that beneficiaries have continued access to all medically reasonable tests at rates that are fair to laboratories performing the tests.

Laboratory Tests as Commodities

At several points in the discussion, clinical laboratory tests were compared to commodities and a suggestion was made that payment rates for these tests should be "commodity-like." Commodities are understood as a class of goods for which there is demand, but which is supplied without qualitative differentiation across a market. A commodity, like wheat, corn, oil, gasoline, gold etc. is fungible, i.e., the markets treat them as equivalent, or nearly so, without regard to who produces them. For commodities, differentiation is based solely on price, not quality. So, are laboratory tests commodities? As explained in the section below, the answer is clearly, no, laboratory tests and test results are not commodities.

First, laboratory tests are services not goods. The process of attaining a laboratory test result is a service that can be purchased, and that process has variability across its delivery, including, specimen collection method and geographic location, storage, labeling, personnel, equipment, materials and reagents, measurements methods, recoding and reporting of results and environmental factors. To be a commodity, laboratory test results would have to be uniform across providers, with little to no differentiation in quality. This is not the case, as evidenced by test results for COVID-19, whether done by RT-PCR, antibody, or antigen testing. Variability in COVID-19 test results have been widely reported by government agencies and the press multiple times this year.

While COVID-19 testing is new and variations in COVID-19 testing are not a surprise, there is also variability in test results for many other analytes, including CLIA-waived tests. CLIA "waived" tests are supposed to employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, and pose no reasonable risk or harm to the patient even if the test is performed incorrectly.[2]

For example, CLIA-waived tests include blood glucose levels determined by blood glucose meters. But a 2012 study by a European Multicenter Healthcare Organization covering 453 subjects and 5 different blood glucose meters had Mean Absolute Relative Difference (MARDs) of from 4.9% to 9.7%, and only 3 of the 5 meters met the ISO 15197 requirements.[3] From 1992-2009, 100 deaths were due to blood

[2] 42 C.F.R. 493.15(b)(1)-(3).

[3] C. Tack. Accuracy evaluation of five blood glucose monitoring systems obtained from the pharmacy: a European multicenter study with 453 subjects. Diabetes Technol Ther. 2012 Apr;14(4):330-7. doi: 10.1089/dia.2011.0170. Epub 2011 Dec 16.

glucose meter errors, and over 12,672 serious injuries were reported from 2004-2008. Blood glucose meters differ in composition, technical methodology, software, styling, and instructions on use.

Variations in quality exist for many other CLIA-covered tests (see AAB's Proficiency Testing Data here). This variability demonstrates that laboratories and laboratory testing services are not fungible and, instead, require sophisticated equipment and analysis to deliver accurate and reliable results to patients. Considering clinical laboratory tests as commodities makes the price of these services more important than the quality and accuracy of the test results and therefore makes price more important the health and welfare of patients. This was never the intent of Congress, and MedPAC should not embrace that policy.

Competitive Bidding for Laboratory Testing

MedPAC members discussed the comparison of laboratory testing services to durable medical equipment (DME), and the comparison between implementation of competitive bidding for DME and PAMA for laboratory tests. For several reasons, NILA believes that this analogy is misplaced. First, unlike DME, a laboratory tests is a service, rather than a commodity as discussed above. The time, location, and skill of the analysis undertaken by laboratorians is key to the reliability, accuracy, and speed at which patients receive results. While automation is increasing in the laboratory sector, laboratory tests still require pre- and post-analytic analysis to assess and provide accurate and reliable results to patients. Additionally, unlike DME, the location of testing services is of vital importance to the quality and timing of results received. While DME can generally be stored in one part of the country and shipped to another, patient specimens are more difficult to transport and long-distance transport inevitably leads to longer turnaround time for laboratory results. Delays in test results can both harm patients and undermine the utility of testing services. For that reason, access to community and regional laboratories in close proximity to patients and specimen collection is vital to ensuring timely access to test results. A competitive bidding system that prioritizes the lowest price over testing location, speed, and quality would undermine patient care and ultimately waste scarce Medicare resources. NILA disagrees with the suggestion by a number of MedPAC members to transition laboratory payments to a competitive bidding system.

In fact, transitioning the laboratory payment system to a competitive bidding system has already been explored and rejected. According to a 2000 report by the Institute of Medicine, the disadvantages of competitive bidding for laboratory services outweigh the advantages.[4] At that time the Health Care Financing Administration considered this issue and found that competitive bidding would likely result in multiple laboratory fee schedules across geographic regions of the country. This would add administrative burden to the Medicare program and result in laboratories being treated inequitably across geographic regions. More importantly, as losing bids were excluded from the program, this type of system would fundamentally alter the laboratory infrastructure in the country and raises the question of whether there would be a sufficient number of labs to properly serve the growing population of Medicare beneficiaries.

Limitations of CLFS Methodology

Unlike larger laboratories with national reach, between 30-50 percent of community and regional laboratory revenue is from Medicare. As a result, the Clinical Laboratory Fee Schedule (CLFS) cuts disproportionately affect the viability of community and regional laboratories. In addition, private payer

[4] Institute of Medicine 2000. *Medicare Laboratory Payment Policy: Now and In the Future.* Washington, DC. The National Academies Press. https//doi.org/10.17226/9997.

rates to hospitals have historically been much higher than rates to independent laboratories. When PAMA was implemented, private payer rates to hospitals were not included. Excluding those hospital rates while focusing on rates for a small number of large laboratories skewed the data significantly and made cuts to independent laboratories much deeper than they otherwise would have been. The result is the absence of a real private market rate for laboratory testing and, instead, constant downward pressure towards rates that are only sustainable for large national laboratories. MedPAC must acknowledge the omission of hospital data and recommend a more equitable collection of data.

Additionally, community and regional laboratories have less negotiating power with private payers and frequently struggle to be "in-network" with private payers at all. Community and regional laboratories—unlike larger national chains—have little power to establish reasonable rates for their services and must instead accept the rates negotiated between payers and large national laboratories. Given this structure, CLFS replicates the disproportionate and distorted bargaining power of the private market in the Medicare market, doubling down on large national laboratories' influence and PAMA's anticompetitive impacts. We appreciate that at least one member of MedPAC recognized during the September 3rd meeting that overrepresentation by large laboratories in the data collection process may have resulted in cuts that are too big. However, another member suggested that perhaps we could just sample the large labs as they make up a significant portion of the volume and the impact of including hospital and physician office laboratories would not have an impact on the data. The assertion that hospital and physician office data would not have had an impact is mere speculation. The high private payer rates for hospital and physician office labs suggest that there would be a significant impact on the overall picture. The only way to know the impact of this data is to collect it alongside data from the other sectors of the laboratory industry. The inclusion of the entire laboratory market is essential to understanding the true market rate of the industry. You cannot create a "market rate" by only collecting data from the two largest players in the markets whose rates do not reflect the cost of providing care in the many unique settings across the country. This is discussed further in comments AAB and NILA submitted to CMS in 2017.[5]

It was alarming and concerning to hear another MedPAC member suggest that shifting reimbursement to the weighted average of the cost of tests performed was not a sufficient cost-saver and suggested moving to an even larger cut. Still, another member suggested that laboratory reimbursement move to an automatic deflation model stating that a "simple solution" would be to select a number, such as five or ten percent and the fee schedule would go down by that amount per year. This so-called solution would result in rapidly falling reimbursement for laboratories and would endanger their very existence. These suggestions are troubling to NILA members who are already beginning to see significant cuts that impact their ability to perform necessary laboratory tests. This suggestion does not take into account the costs associated with laboratory tests that will grow, rather than decrease, over time. Labor costs for trained staff to analyze specimens, supply costs, and rent are just a few examples of the financial obligations laboratories will be unable to sustain should payments shrink by even a small percentage every year. This proposal could mean the end to the market for regional and community laboratories all together.

The result of larger laboratories' disproportionate bargaining power and the "race to the bottom" has been further market consolidation and poorer service for Medicare beneficiaries. If this continues, Medicare and its beneficiaries would suffer from limited access to fast and accurate diagnostic tests and

[5] NILA letter to Administrator Seema Verma, at: https://www.nila-usa.org/images/NILA%20Comment%20Letter%20on%20Preliminary%20CLFS%202018%20Rates.pdf.

a duopoly or otherwise limited laboratory market that could eventually command higher payment rates from the private sector, to which Medicare rates are linked. Falling rates, over the past 25-30 years, worsened by PAMA, also made it increasingly difficult for the laboratory industry to respond to a natural disaster or public health emergency. We are witnessing the dangerous implications of that now, as we respond to the COVID-19 pandemic. The number of independent laboratories has been reduced and those labs that remain did not have the resources or the reserves in place to act quickly when COVID-19 emerged. Thus, we have seen limited access to COVID-19 testing and long wait times (particularly from the largest national laboratories) for results in many areas where the virus has surged.

While NILA recognizes that it is neither the responsibility nor charge of MedPAC to keep its members in business, patients and Medicare do have an interest in maintaining access to accurate, reliable, and fast diagnostic testing services. The COVID-19 pandemic and the associated crisis of testing availability and speed demonstrate the pitfalls that await Medicare if patients can only turn to large, national chain laboratories with limited community reach.

Flawed Implementation of PAMA

Given that the primary mandate to MedPAC is the evaluation of PAMA implementation, NILA believes that it is important for MedPAC to better understand CMS' flawed implementation of PAMA, which continues to impact laboratories today. PAMA's structural flaws were replicated and magnified by CMS' implementation of CLFS. The rates and analysis undertaken by CMS did not adequately sample the laboratory marketplace as required under statute and as Congress intended, resulting in skewed rates that disproportionately harm community and regional laboratories. Less than one percent—a mere 0.7 percent of laboratories paid under Medicare Part B on the CLFS—reported applicable information to CMS, resulting in radically skewed payment rate calculations with test volume and rate data dominated by the two largest national independent laboratories. While CMS has since modified its regulations to require reporting from a wider variety of laboratories, we have yet to see if these laboratories will report, and the underlying methodology and mechanisms continue to favor and over-emphasize data submitted by large national laboratories.

CMS finalized PAMA regulations on June 23, 2016, and when issued, the regulation lacked significant information needed for laboratories to meet its multitude of requirements. CMS subsequently released needed information three months later through subregulatory guidance in mid-September 2016. The release of the guidance needed to comply with CMS' regulatory requirements resulted in clinical laboratories having less than three and a half months to prepare for, verify, and report millions of data entries to CMS, while under the threat of significant financial penalties. Further, laboratories experienced significant difficulties submitting data into the CMS data reporting systems, facing multiple rejections and requests for resubmission after CMS notified some laboratories that data had not been fully received by their system.

The difficulties of complying with such a compressed timeline were magnified by CMS's mandate for laboratories to collect and report retroactive data for payments received and finalized from January 2016 – June 2016. Many community laboratories, unlike larger national laboratories, did not have billing systems in place at the time that could comply with CMS requirements for older billing data within their billing systems. As a result, many laboratories were forced to manually review millions of data sets on paper claims and attempt to call on payers for clarification to determine what information should be reported. The extreme difficulties experienced by laboratories in trying to collect and report data in the unreasonably brief window resulted in significant errors that continue to adversely impact community and regional laboratories. While CMS granted a 60-day grace period at the end of the reporting period,

CMS communicated the extension to laboratories only 24 hours in advance of the original deadline. For the majority of laboratories, the 60-day extension came too late to address concerns regarding potentially flawed data many had already scrambled to submit in order to comply with the original deadline and requirements to avoid potentially extreme financial penalties that small laboratory businesses could never meet.

Conclusion and Recommendations

In order to relieve the burden of reporting and ensure an accurate picture of the full clinical laboratory market, AAB and NILA recommend that MedPAC explore other options for data collection. One possible area of exploration would be to ensure a statistically valid, stratified random data sample is collected by CMS that represents all segments of the laboratory market accounting for geographic diversity. This would ensure that each type of laboratory is represented, yet only a few labs would be required to submit data. Another option would be to collect the data from an outside source like Fair Health or another entity that is already collecting private market data across different providers.

All of the implementation flaws—from the limited scope of data, to collection methodologies that failed to account for technological implementations—repeatedly placed community and regional laboratories at a comparative disadvantage to larger national laboratories. These flaws affect the CLFS today and these flaws will continue well into the future if CMS continues to implement a rate methodology based on incomplete and inaccurate data that fails to account for laboratory business practices.

We appreciate MedPAC's work to analyze and understand the flawed implementation of PAMA and urge MedPAC to consider the unique and disparate impact this implementation has had on community and regional laboratories, and we thank you for taking our concerns into consideration. NILA looks forward to working with MedPAC and other stakeholders to examine the design flaws inherent to PAMA and identifying a more accurate, reliable, and sustainable diagnostic testing reimbursement structure. If you require more information, please contact Erin Morton at emorton@dc-crd.com.

Sincerely Yours,

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